The Cold Chain and Vaccine storage

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www.immunisation.ie
Objectives

• To outline the complexity of vaccine management

• To understand the importance of ordering appropriately and the delivery service

• To explain the importance of the cold chain, monitoring it within your own practice, the correct procedures for handling and storage of vaccines including procedure following cold chain breach and returns service

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The Vaccine Management Environment

- Supply Chain Management
- Financial Management
- Procurement & Tenders
- Delivery System
- General Public
- Marketing & Promotions
- Target Cohorts
- GP Immunisation Teams
- Education & Vaccine Promotion
- Healthcare Workers
- Vaccine Manufacturers
- Education & Immune Promotion
- HIQA
- NIAC
- Clinical & Technical Linkages
- DOH
- NIAC
- HPRCA
- NIAC
- DOH
- General Public
- Target Cohorts
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Factors affecting Vaccine Management Performance

- Vaccine procurement
- Correct forecasting
- Contingency plans
- Funding
- Liaison with HPRA
- Use of temperature monitoring devices
- Cold chain delivery fleet and fridge
- Alarms and alerts systems
- Use of freeze of heat indicators during transport
- Customer education
- Standard operating procedures

Procurement & availability of adequate quantities of vaccine

Reliability of cold chain

Vaccine, distribution, control and monitoring

Vaccine Stock Management

- Order and customer relationship management
- Scheduled delivery route & dates
- Effective systems for ordering, receiving and checking receipts
- Returns monitoring
- Short date stock management
- Invoice processing
- Stock reconciliation
Procurement & Contract Management

- Tender a year in advance
- 1-2 years Forecast for manufacturers
- Commit to orders 6-8 months in advance
- Sufficient contingency stock
- Expiry date management - continuously reviewing distribution requirements
- Monthly meetings / reports with manufacturers/ finance

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Monitoring

National Level monitoring include:

• Distribution Vs Cohort
• Returns from sites
• Forecasting budgets Vs Actual
• Audited by C& AG

www.immunisation.ie
% of Doses distributed vs Cohort requirements

www.immunisation.ie
Cost of vaccines 2016 - 2018 & forecast 2019 - 2021

www.immunisation.ie
<table>
<thead>
<tr>
<th>Age</th>
<th>Date of Birth</th>
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<tbody>
<tr>
<td>2 mths</td>
<td>BCG (1) 5in1 + MenC (2) 6in1 + PCV7 (2) 6in1 + PCV13 (2) 6in1 + PCV13 (2) 6in1 + PCV13 + MenB + Rota (3+ oral)</td>
</tr>
<tr>
<td>4 mths</td>
<td>5in1 + MenC (2) 6in1 + MenC (2) 6in1 + MenC (2) 6in1 + MenC (2) 6in1 + MenC (2) 6in1 + MenB + Rota (2+ oral)</td>
</tr>
<tr>
<td>6 mths</td>
<td>5in1 + MenC (2) 6in1 + PCV7 + MenC (3) 6in1 + PCV13 + MenC (3) 6in1 + PCV13 (2) 6in1 + PCV13 + MenC (3)</td>
</tr>
<tr>
<td>12 mths</td>
<td>MMR (1) MMR + Hib (2) MMR + PCV7 (2) MMR + PCV13 (2) MMR + PCV13 (2) MMR + MenB (2)</td>
</tr>
<tr>
<td>13 mths</td>
<td>MMR + Hib (2) MMR + Hib (2) MMR + Hib (2) Hib/MenC +PCV13 (2)</td>
</tr>
<tr>
<td>4-5 yrs</td>
<td>MMR + 4in1 MMR + 4in1 MMR + 4in1 MMR + 4in1 MMR + 4in1 (low dose) MMR + 4in1</td>
</tr>
<tr>
<td>1st yr 2nd level</td>
<td>T/d (or 6th class) T/d + HPV 4 (girls) x3 Tdap + HPV x3 Tdap + MenC + 2x HPV4 Tdap + MenC + 2x HPV4 Tdap + MenACWY +2 x HPV9 (universal)</td>
</tr>
</tbody>
</table>

HPV remained at 3 doses for 15yrs and older
• 3 schedule changes resulting in replacements rather than inclusion of additional dose
• Number of sites receiving vaccines = 2810
• Inevitably there will be cold chain issues
• Significant reduction in expired stock

www.immunisation.ie
Cold Chain Monitoring and Distribution

- Use of temperature monitoring devices
- Cold chain delivery fleet and fridge
- Alarms and alerts systems
- Use of freeze or heat indicators during transport
- Customer education
- Standard Operating Procedures

Reliability of cold chain

Vaccine distribution, control and monitoring

- Order and customer relationship management
- Scheduled delivery route & dates
- Effective systems for ordering, receiving & checking receipts
- Returns monitoring

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Why is the cold chain important?

- Vaccines must be stored within a specific temperature range between +2 and +8°C to ensure their potency and to comply with regulations (PA/EU licence).
- Vaccines are sensitive biological products that may become less effective or even destroyed when exposed to less than +2 and greater than +8°C and/or exposed to direct sunlight or fluorescent light.
- Freezing may cause the vial to crack leading to contamination.
- Assurance in product potency ensures maximum benefit from immunisation.
- Poor publicity if recall required make affect uptake.

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Reliability of Cold Chain

Cold Chain relies on 3 main elements in each of these 3 areas

- manufacturing site
- distribution site
- Provider facility/ administration site

- Well trained personnel
- Reliable storage equipment & transportation
- Efficient management procedures

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Who’s Responsible for Cold Chain

Temperature records are available for every vaccine from point of manufacturing to delivery at GP surgery. Storage fridges and transport vehicles are all equipped with heat / cooling devices and alarms/alert systems which are monitored 24/7.

The lower 3 links refer to when the vaccines are your responsibility and vaccines should be covered by the practice insurance.

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National Cold Chain Service

• Commenced 1\textsuperscript{st} January 2005, delivering 1.6 m doses to ~1650 sites annually now has increased to 2,810 sites receiving 2.5 million doses annually

• United Drug Distributors based in Citywest with satellite sites in Limerick and Ballina- all orders are assembled in Dublin.

• Storage fridge has 4 individual refrigerating units and backed up by an independent generator. Alarms/alert systems are monitored 24/7

• Fridges in Dublin, Limerick and Ballina are also mapped and inspected by HPRA

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Vaccine Deliveries

- The 12 monthly deliveries are based on 4 week cycles.
- During the flu season deliveries are fortnightly (Sept-Jan)
- (there are 4 “down” weeks, whereby the gap will extend to 5 weeks or 3 weeks during flu season).

- 2019 Flu deliveries are planned to commence mid Sept and every site will have received flu vaccines within a two week period if they have placed an order as per schedule.
- Please check your calendar and place your order on time. No unscheduled deliveries can be accommodated during Sept- Jan period.
- School teams can request for additional orders in Spring 2020 once their requests by first week in Jan 2020
Unscheduled / Emergency Deliveries

• Contract is for 15 scheduled deliveries to each site, including fortnightly deliveries from September to January
• Each emergency delivery is an extra charge (costly) and cause a disruption to routine deliveries

• Unscheduled deliveries cannot be accommodated between September and January.
Importance of Ordering Appropriately

Vaccine orders are monitored to ensure consistency with target cohort requirements. Significant deviations may indicate over or under stocking, leading to vaccine wastage or missed opportunity to vaccinate.

Each site should order online monthly to ensure proper stock levels.

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How much vaccine should be ordered?

- Vaccine stocks should be kept to a minimum by regularly ordering only the quantity of vaccine required until the next delivery. The designated person should know how much vaccine stock they require at any one time, according to the size of the target population.
  - Restrictions placed by online system
  - Maximum of 6 weeks supply should be in the fridge at time of delivery
  - During ‘flu season this can be reduced to 3 weeks supply as deliveries will be fortnightly

www.immunisation.ie
Online ordering commenced in 2015 and since then:

Value of vaccine distributed decreased by 4%
Number of doses distributed decreased by 4% (correcting for MenB and Rota and 8% drop in birth cohort)

Number of doses returned for destruction decreased by 32%

Value of vaccines returned for destruction decreased by 28%

www.immunisation.ie
# Vaccines supplied

<table>
<thead>
<tr>
<th>Category</th>
<th>Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Childhood vaccines</td>
<td>6 in 1, Men C, PCV, MMR, Hib/MenC, Men B, Rotavirus</td>
</tr>
<tr>
<td>Adult vaccines</td>
<td>Td, Tdap</td>
</tr>
<tr>
<td></td>
<td>Influenza, Pneumococcal polysaccharide vaccine</td>
</tr>
<tr>
<td>HSE / school programme vaccines</td>
<td>Tdap/IPV, MMR, Tdap, HPV, Men C</td>
</tr>
<tr>
<td>Restricted vaccines</td>
<td>Hepatitis A, Hepatitis B, Hepatitis A +B</td>
</tr>
<tr>
<td></td>
<td>Td/IPV, Tdap/IPV, MenACW\textsubscript{135}Y,</td>
</tr>
</tbody>
</table>

Current list of available vaccines:
- from United drug
- in newsletter
- on immunisation website

[www.immunisation.ie](http://www.immunisation.ie)
School Immunisation Programme
Second Level.
Quadrivalent Influenza Vaccine (split virion, inactivated), suspension for injection in pre-filled syringe

10 pre-filled syringes (0.5 ml) with attached needle

Intramuscular (IM) or subcutaneous (SC) use

www.immunisation.ie
MenACWY (contract to be awarded)

www.immunisation.ie
Value of Vaccines per Child

- PCI: 6in1, MenB, Rotarix, Men C, PCV, MMR, Hib/MenC
- Junior School: 4in1 and MMR
- Secondary School: Tdap, MenC and HPV

- **Indicative price €1,350**

[www.immunisation.ie](http://www.immunisation.ie)
Ensure fridge stock is included in insurance policy

<table>
<thead>
<tr>
<th>Qty</th>
<th>Vaccine</th>
<th>Qty</th>
<th>Vaccine</th>
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<tbody>
<tr>
<td>10</td>
<td>INFANRIX HEXA</td>
<td>60</td>
<td>INFANRIX HEXA</td>
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<tr>
<td>10</td>
<td>PREVENAR</td>
<td>60</td>
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<tr>
<td>10</td>
<td>MenB</td>
<td>60</td>
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</tr>
<tr>
<td>10</td>
<td>Rotavirus</td>
<td>40</td>
<td>Rotavirus</td>
</tr>
<tr>
<td>4</td>
<td>MEN C</td>
<td>20</td>
<td>MEN C</td>
</tr>
<tr>
<td>8</td>
<td>MMR</td>
<td>40</td>
<td>MMR</td>
</tr>
<tr>
<td>4</td>
<td>MENITORIX</td>
<td>20</td>
<td>MENITORIX</td>
</tr>
<tr>
<td>4</td>
<td>IPV BOOSTRIX</td>
<td>20</td>
<td>IPV BOOSTRIX</td>
</tr>
<tr>
<td>5</td>
<td>DITE BOOSTER</td>
<td>10</td>
<td>DITE BOOSTER</td>
</tr>
<tr>
<td>3</td>
<td>BOOSTRIX</td>
<td>20</td>
<td>BOOSTRIX</td>
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<tr>
<td></td>
<td>Total</td>
<td>Total</td>
<td>€10,082.25</td>
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<tr>
<td></td>
<td>€1,786.28</td>
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</table>
Recommended procedure for ordering and accepting vaccines

- Should have a named, trained and designated person and deputy
- Order on-line before closing date
- **Remove expired vaccines from fridge** and prepare for return to NCCS driver
- Check vaccine deliveries against the order for damage or discrepancies
- Place vaccines in the vaccine fridge immediately, ensuring the shortest dated vaccine is at the front
- **NEVER leave vaccine delivery at room temperature**
- **Rotate stock** so earliest expiry date in front of longer dated stock

[www.immunisation.ie](http://www.immunisation.ie)
Storage of Vaccines & Monitoring of Vaccine Fridge temperature

- Vaccines must be stored in a **Pharmaceutical** fridge
- To comply with product licence, they must be
  - Stored within the temperature range of 2-8°C
  - Stored in original packaging to protect from light & box contains batch details
- Store on shelves, not touching the sides
- Record fridge temperature **twice** daily
- Set fridge to alarm at +3°C or +7°C to allow time to react before +2°C or +8°C is reached
- Wire fridge directly to power without use of a plug and have a dedicated circuit. **Never unplug the fridge**
- Never store out of date vaccines in the fridge

[www.immunisation.ie](http://www.immunisation.ie)
Temperature Readings

- Maximum / Minimum temperatures should be recorded twice daily.
- ENSURE the memory is erased twice daily, in the morning and just before closing surgery, i.e. the maximum, minimum and current temperatures should be checked again and if the thermometer has been correctly reset these three readings should all show the same temperature (i.e. current temperature)
- Recording only shows the highest temperature registered but not the duration.
- Use a data-logger.
Data Loggers

- USB temperature data logger for use with pharmacy fridges independent of fridge power supply
- Measurement range from -35°C to +80°C and record at preset intervals (5 - 15 min)
- Can store up to a year's worth of data (16,382 readings)
- Flashing LED status indicators mean user can see the status of the logger without having to download data
- They do not replace recording Max/ Min readings twice daily.
- Assist in providing advice on vaccine viability in case of temperature deviation to reduce wastage/re-vaccination

www.immunisation.ie
Example of Newer Data-logger on the Market

Fridge-tag® 2L

This device will record temperatures over 24 hours and record the Min and Max temperature.

30 days display on screen.

PDF file can be downloaded at any time.

Can Monitor Fridges, Freezers and a variety of Controlled Ambient areas

Key Features
- Temperature measurement intervals = Every Minute for table
- Logging interval of 5, 10 or 15 min for graph view
- Accuracy 0.5
- Displays daily Min / Max temperature
- Displays 30 days on screen
- PDF download with possibility to have 28, 56, 84 or 112 days
- PDF with Min/ Max table & Weekly graph view
- 2 individual programmable alarms
- Audible alarm
- Operating temperature -25°C to +55°C
- Every device is calibrated (NIST standard) / Certificate for 3 years
- Operating life time = 3 years
- External sensor optional (recommended for freezers)

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Planned power outage

- Keep the room as cold as possible
- Fill your fridge. Place containers of very cold salty water days before the outage in spaces. Double wrap ice blocks with bubble wrap and place on bottom of fridge
- Lock the fridge
- Record the temperature
- Use a Datalogger

www.immunisation.ie
Break in the Cold Chain- what to do?

Can occur due to power supply failure, fridge door left open or fridge malfunctions

• Vaccines should be transferred immediately to a working fridge or restore power
• Check the temperature and find out how long the fridge breakdown has been
• Has any vaccine affected already been given to patients?

• Email the following:
  – Name of practice
  – Account number
  – Current fridge temperature
  – Duration of temperature breach
  – Maximum temperature reached
  – Name, quantity and batch numbers of vaccines in the fridge.

  to cliona.kiersey@hse.ie or immunisation@hse.ie

www.immunisation.ie
Stability Data

• As per licence vaccines must be stored between $+2^0$ & $+8^0C$

• Company data show that vaccines can be used if exposed to short deviations. Each temperature deviation must be judged on a case by case scenario. Each vaccine has specific criteria and will remain stable for different lengths of time. Advice is given for vaccines delivered only by NCCS.

• Expired and damaged unopened vaccines must not be used and should be removed from the fridge and returned to the NCCS delivery person with a completed vaccine return form. Vaccine return forms are available to download from http://www.immunisation.ie/en/VaccineOrderingandStorage/.

• Expired and damaged unopened vaccines must not put into a sharps bin.

www.immunisation.ie
What if vaccine affected by cold chain break already given to a patient?

- Twice daily temperature monitoring should reduce chance of this happening
  - Treat as Serious Untoward Incident
  - Inform Practice Manager/Line Manager
  - Suspend all immunisation clinics until resolved
  - Ensure that everyone knows not to use vaccines until advice has been received
  - Make list of all patients and which vaccines given
  - Email immunisation@hse.ie who will provide advice if re-vaccination required

www.immunisation.ie
“Borrowed Vaccines”

If vaccines are required due to stock out or a fridge issue you can get vaccines from another practice.

Please do not return vaccines to this practice as vaccines should be ordered by them and delivered directly to them from HSE National Cold Chain Service.
Returns service

- As part of their contract, manufacturers must accept from NCCS expired or damaged vaccines and dispose of them.
- Vaccines received from NCCS which cannot be used-(adversely affected by temperature breach, damaged or expired) must be returned to NCCS for destruction.
- Expired and damaged unopened vaccines must not put into a sharps bin.
- Returns data is important should there be a batch query.

www.immunisation.ie
% of Expired Vaccines Returned that expired more than 6 months

www.immunisation.ie
Vaccines returned expired more than 6 months.

- **2012** - 44,184 doses - 2TU Mantoux test (expiry 05/2002) was **10 years and 2 months** expired.
- **2013** - 16,753 doses - Pneumovax (expiry 03/2007) was **6 years and 3 months** expired.
- **2014** - 10,737 doses - Pentavac (expiry 09/2002) was **11.5 years** expired. Removed from schedule in 2009.
- **2015** - 9,168 doses - MMR (expiry 03/2004) was **11.5 years** expired & Pentavac (6yrs 8 mths expired) also returned.
- **2016** - 6,366 doses - Hep A was 6 years and 3 months expired
- **2017** - 3,137 doses - Infanrix Hexa was 5 yrs 2 months expired
- **2018** - 5,944 doses - Hiberix - 4 yrs 4 months expired & 11 sites = 712 doses 2014/15 flu, 117 sites had 4012 flu prior to 2017/18 season
- **2019** - Havrix - 4 yrs 2 months (02/2015)

[www.immunisation.ie](http://www.immunisation.ie)
HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock

Recommendations for a planned power outage
REMEMBER THE 5 Rs

• **Read**: Twice daily readings of the fridge thermometer’s maximum, minimum and current temperatures at the same time morning and evening daily during the working week.

• **Record**: record fridge temperatures in a standard fashion and on a standard form stating date and time of reading and sign/initial (Appendix 1) and download data logger regularly.

• **Reset**: reset the max/min thermometer (i.e. clear the thermometer memory) after each reading and after a period of high activity once temperatures have stabilised and also at the end of every day.

• **React**: the person making the recordings should take action if the temperature falls outside +2°C to +8°C and document this action (Appendix 3).

• **Remove** expired stock from fridge in a timely fashion and return to NCCS for destruction

www.immunisation.ie
Conclusions

• Vaccines are expensive

• Good housekeeping is essential for vaccine management

• Ensures patient safety and success of vaccination programmes

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